

PACKAGE LEAFLET: Information for the patient

MONTALEX

Chewable tablets – 5 mg

Film-coated tablets – 10 mg

(Montelukast sodium)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medication has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Montalex is and what it is used for
2. Before you take Montalex
3. How to take Montalex
4. Possible side effects
5. How to store Montalex
6. Further information

1. WHAT MONTALEX IS AND WHAT IT IS USED FOR

Montalex contains the active substance montelukast. Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes to connect with their receptor. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy. By blocking leukotrienes, Montalex improves asthma symptoms and helps control asthma, also Montalex 10 mg improves seasonal allergy symptoms (also known as seasonal allergic rhinitis).

Your doctor may prescribe Montalex to treat asthma, preventing your asthma symptoms during the day and night.

- Montalex is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Montalex (only the 5 mg tablet) may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- Montalex also helps prevent the narrowing of airways triggered by exercise.

In those adult patients in whom Montalex is indicated in asthma, Montalex can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montalex should be used depending on the symptoms and severity of you or your child's asthma.

2. BEFORE YOU TAKE MONTALEX

Do not take Montalex if you are allergic to the active substance or to any of the excipients of the tablet.

Tell your doctor if you suffer from any other disease or allergy.

Take special care with Montalex

Before you take Montalex, it is important that you tell your doctor if you or your child's asthma or breathing gets worse. In this case tell your doctor immediately.

Oral Montalex is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given to you or to your child. Always have your inhaling rescue medicine for asthma attacks with you.

It is important that you or your child take all asthma medications prescribed by your doctor. Montelukast should not be used instead of other asthma medications your doctor has prescribed you.

Any patient on anti-asthma medicines should be aware that if he or she develops a combination of symptoms such as: flu-like symptoms, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, he / she should consult the doctor.

You or your child should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with montelukast (see section 4). If you or your child develop(s) such symptoms while taking Montalex, you should consult your doctor.

Use in children

For children 6 to 14 years old, Montalex 5 mg chewable tablets are available.

Taking other medicines

Some medicines may affect how Montalex works, or Montalex may affect how other medicines work.

Please tell your doctor or pharmacist if you or your child are taking or have recently taken other medicines, including those obtained without a prescription.

Tell your doctor especially if you are taking the following medicines:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections).

Taking Montalex with food and drinks

Montalex 5 mg chewable tablets should not be taken immediately after food. They should be taken at least 1 hour before or 2 hours after food.

Montalex 10 mg film-coated tablets can be taken with food or between the meals.

Pregnancy and breastfeeding

Pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montalex. Your doctor will assess whether you can take Montalex during this time.

Breastfeeding

It is not known if montelukast appears in breast milk. You should consult your doctor before taking Montalex if you are breastfeeding or intend to breastfeed. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Montalex is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with montelukast may affect some patients' ability to drive or operate machinery.

Important information about some of the excipients of Montalex

Montalex 5 mg chewable tablets contain aspartame, which is a source of phenylalanine and may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Montalex 10 mg film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The film-coating of Montalex 10 mg tablets contains an AZO coloring agent, Sunset yellow FCF (E 110) which may cause allergic reactions. It also contains lecithin (soy). If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO TAKE MONTALEX

You or your child should take only one tablet of Montalex once daily as prescribed by your doctor.

Montalex 5 mg

For children 6 to 14 years of age.

One chewable tablet daily to be taken in the evening. The tablet should not be taken immediately after food, it should be taken at least 1 hour before or 2 hours after food.

Montalex 10 mg

For teenagers 15 years of age and older and adults

One 10 mg tablet to be taken once daily in the evening. Montalex 10 mg can be taken with food or between the meals.

During the time you are taking Montalex be sure that you or your child are not taking any other products that contain the same active ingredient.

If you take more Montalex than you should

Contact your doctor immediately for advice.

There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you forget to take Montalex

Try to take Montalex as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Montalex

Montalex can treat asthma only if you continue to take it regularly. It is important not to interrupt it by yourself, but to continue taking Montalex for as long as your doctor prescribes it.

If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Montalex can cause side effects, although not everybody gets them.

The most frequent side effects are headache and abdominal pain.

Other side effects are:

- infection of the upper respiratory routes
- increased bleeding tendency
- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes (dream abnormalities, including nightmares, hallucinations, irritability, feeling anxious, restlessness, agitation including aggressive behaviour, tremor, depression, trouble sleeping, suicidal thoughts and actions (in very rare cases), dizziness, drowsiness, pins and needles/numbness, seizure, palpitations, nosebleed, diarrhoea, dry mouth, indigestion, nausea, vomiting, hepatitis, bruising, itching, hives, tender red lumps under the skin most commonly on the shins (erythema nodosum), joint or muscle pain, muscle cramps, tiredness, feeling unwell, swelling, fever, stuttering (in very rare cases).

Churg-Strauss syndrome has occurred very rarely in association with the use of leukotriene receptor antagonists. In many of the reported cases the reaction followed the reduction or withdrawal of oral corticosteroid therapy. This syndrome appears with these symptoms: flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash.

Prescribers should be alert to the development of eosinophilia, vasculitic rash, cardiac complications, or peripheral neuropathy.

You must tell your doctor immediately if you get one or more of these symptoms. Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MONTALEX

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date shown in the package.

Store in the original package in order to protect from light and humidity.

6. FURTHER INFORMATION

The active substance is montelukast sodium.

What Montalex 5 mg chewable tablets contain

Each chewable tablet contains 5.2 mg montelukast sodium which corresponds to 5 mg of montelukast.

The excipients are: mannitol, microcrystalline cellulose, low substituted hydroxypropyl cellulose, iron oxide red, croscarmellose sodium, cherry flavour, aspartame and magnesium stearate.

What Montalex 10 mg film-coated tablets contain

Each film-coated tablet contains 10.4 mg montelukast sodium which corresponds to 10 mg of montelukast.

The excipients are:

tablet core: microcrystalline cellulose, lactose monohydrate, low substituted hydroxypropyl cellulose, croscarmellose sodium, magnesium stearate

film coat: polyvinyl alcohol, talc, macrogol, titanium dioxide, quinoline yellow, Sunset yellow FCF (E 110), lecithin (soy), iron oxide red and polyethylene glycol.

Content of the pack

Montalex 5 mg: box of 30 chewable tablets.

Montalex 10 mg: box of 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

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